

REMARKS

Status of the claims:

With the above amendments, claim 1 has been amended, claims 5, 33-35, 38, and 40-62 have been previously canceled, and claims 1-4, 6-32, 36, 37, 39, and 63-81 are pending and ready for further action on the merits. No new matter has been added by way of the above amendment. Claim 1 has been amended so that a is equal to 1. Reconsideration is respectfully requested in light of the following remarks.

Rejections under 35 U.S.C. §112, first paragraph

Claim 30 is rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled.

Applicants traverse.

The Examiner asserts that claim 30 lacks enablement for the following terms: biologic response modifiers, glucocorticoids, DPP-IV inhibitors, GK activators, insulin mimetics, insulin secretagogues, insulin sensitizers, GLP-1 mimetics and fibrates.

Applicants remind the Examiner that “[a] patent need not teach, and preferably omits, what is well known in the art.” In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Applicants submit that each of biologic response modifiers, glucocorticoids, DPP-IV inhibitors, GK activators, insulin mimetics, insulin secretagogues, insulin sensitizers, GLP-1 mimetics and fibrates were well known in the art at the time of the filing the present invention and therefore, the present invention need not teach again those compounds that are well known in the art. For the Examiner’s benefit, Applicants point out various examples of these enumerated classes of compounds that were known prior to the filing of the present invention.

Biologic response mediators are substances that trigger the body's response to an infection. These substances include for example, interferons, interleukins, and tumor necrosis factors.

Glucocorticoids include hydrocortisone (cortisol), cortisone acetate, prednisone, prednisolone, methylprednisolone, dexamethasone, betametasone, triamcinolone, beclometasone, fludocortisone acetate, deoxycorticosterone acetate, and aldosterone.

Dipeptidyl peptidase-IV (DPP-IV) is a serine protease belonging to the group of post-proline/alanine which cleaves amino-dipeptidases, specifically removing the two N-terminal amino acids from proteins having proline or alanine in position 2. DPP-IV inhibitors were well known in the art at the time of filing the present invention. For example, the compounds in WO 98/19998, WO 00/34241, U.S. Pat. Nos. 6,124,305, 6,380,398, and WO 99/38501 were all known to be DPP-IV inhibitors at the time of filing the present invention.

Glucokinase (GK) is one of group of hexokinases found in mammals. The hexokinases catalyze the first step in the metabolism of glucose, that is, the conversion of glucose to glucose-6-phosphate. Thus, GK activators are compounds that will increase the flux of glucose metabolism in β -cells and hepatocytes, which will be coupled to increased insulin secretion. Accordingly, these activators are useful for treating type II diabetes. GK activators were well known in the art at the time of filing the present invention. These GK activators include the compounds as disclosed in US Patent Nos. 6,388,088, 6,489,485, 6,486,184, 6,482,951, 6,448,399, 6,441,184, 6,441,180, 6,433,188, 6,388,088, 6,388,071, 6,384,220, 6,369,232, 6,353,111, and 6,320,050.

Insulin mimetics include, for example, the compounds that can be found in US Patent No. 6,376,529.

Insulin secretagogues include compounds such as glimepride, linogiride, A-4166, forskolin, dibutyl cAMP, and isobutylmethylxanthine (IBMX), all of which were well known in the art at the time of filing the present invention.

Insulin sensitizers include (i) PPAR γ agonists and (ii) biguanides. The PPAR γ agonists include glitazones (for example, troglitazone, pioglitazone, englitazone, MCC-555, BRL49653 (rosiglitazone), and for example also include compounds such as those

disclosed in WO97/27857, 97/28115, 97/28137 and 97/27847. The biguanides include such compounds as metformin and phenformin.

Glucagon-like peptide-I (GLP-I) is a gastrointestinal hormone that is released postprandially from the L-cells of the gut. The GLP-I mimetics are compounds that mimic the effect of GLP-I. They include compounds such as those found in WO00/42026 and WO00/59887, which were well known prior to filing the present invention.

Fibrates denote a family of compounds which have hypocholesterolemic and hypolipidemic properties.

Thus, Applicants submit because these compounds were well known in the art prior to filing the instant invention, the claims of the present invention including the full scope of claim 30 can be made and used without undue experimentation. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-3, 5-32, 36, 37, 39, and 63-81 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Thirieau '140 (WO 2002/10140) and Thirieau '401 (WO 99/64401).

Applicants traverse.

Applicants have amended claim 1 so that a is 1. With this amendment, there is no longer any overlap between the instantly claimed genus and the genera disclosed in Thirieau '140 and/or Thirieau '401. In other words, neither Thirieau '140 nor Thirieau '401 disclose or suggest the compounds as are presently claimed in the instant invention. Withdrawal of the rejection is warranted and respectfully requested.

CONCLUSION

With the above amendments and remarks, Applicants believe that all objections and/or rejections have been obviated. Thus, each of the claims remaining in the application is in condition for immediate allowance. A passage of the instant invention to allowance is earnestly solicited.

Applicants respectfully petition for one month extension of time. Applicants believe that no fee beyond the extension fee is necessary, however, should an additional fee be deemed to be necessary, the Commissioner is hereby authorized to charge any fees required by this action or any future action to Deposit Account No. 16-1435.

Should the Examiner have any questions relating to the instant application, the Examiner is invited to telephone the undersigned at (336) 607-7486 to discuss any issues.

Respectfully submitted,

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